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VIA ECF AND OVERNIGHT MAIL – [redacted]

Chief Judge Renée Marie Bumb
U.S. District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

RE: *Microspherix LLC v. Merck Sharp & Dohme Corp., et al.*, No. 17-cv-03984 (RMB/JBC)

Dear Chief Judge Bumb:

Pursuant to the Court's Order during the status conference held on September 19, 2023, Defendants Merck Sharp & Dohme Corp., Merck Sharp & Dohme B.V., and Organon USA, Inc. (collectively, "Organon") respectfully request summary judgment of non-infringement of the claims that require a "target tissue." The Court construed the term "target tissue" to mean "tissue targeted for treatment[1] into which implant is implanted." D.I. 194. The facts are not in dispute. The accused Nexplanon implant is implanted in the arm. The contraceptive agent released by Nexplanon targets and treats the female reproductive tract, the mammary glands, the hypothalamus, and the pituitary gland—all remote from the arm. Nexplanon is not implanted in the tissue targeted for treatment. Accordingly, Nexplanon does not satisfy the target tissue limitation.

This issue is ripe for consideration prior to trial, and its resolution will both simplify the issues presented to the jury and substantially shorten the damages period at issue. Plaintiff Microspherix LLC ("Microspherix") asserts nine claims, six of which require a "target tissue."[2] Among these six claims are all of the asserted claims from U.S. Patent No. 8,821,835 ("the '835 patent"). The '835 patent issued almost three years prior to the other two asserted patents. Those three years account for one-third of Microspherix's proposed damages. *See* Schenk Op. Rpt. (Ex. 1) Tab 4. Thus, should the Court grant summary judgment of non-infringement of the "target tissue" claims, the Court would both simplify the upcoming trial and dramatically narrow the parties' dispute on damages.

Summary Judgment of Non-Infringement Is Appropriate for the "Target Tissue" Claims

The parties' experts agree that the Court's construction defines two requirements for a "target tissue": (1) the tissue must be "targeted for treatment," and (2) the tissue must be the one "into which implant is implanted." *See* Cima Dep. Tr. (Ex. 2) 107:20–108:12; Park Rpt. (Ex. 3) ¶ 73.

As to the facts, Microspherix's expert, Dr. Michael Cima, acknowledges that Nexplanon prescribing information instructs healthcare providers to implant the Nexplanon implant into the arm. *See, e.g.*,

[1] This language is consistent with the language in Organon's reply claim construction brief. *See* D.I. 107 at 4 ("'[T]arget tissue' must refer to the tissue that is the ***target of treatment***.") (emphasis in original).
[2] The claims that require a "target tissue" are claims 1 and 16 of U.S. Patent No. 8,821,835 ("the '835 patent") and claims 1, 13, 16, and 18 of U.S. Patent No. 9,636,401 ("the '401 patent").

Cima Op. Rpt. (Ex. 4) ¶ 57. Dr. Cima also admits that the contraceptive agent in Nexplanon, etonogestrel, treats the female reproductive tract, the mammary glands, the hypothalamus, and the pituitary gland—organs that produce the hormones necessary for ovulation. Cima Reply Rpt. (Ex. 5) ¶ 48; Cima Dep. Tr. 73:25–75:22, 112:2–7. None of those tissues "targeted for treatment" are in the arm. Park Rpt. ¶¶ 77–80. Thus, because the tissue "targeted for treatment" is not the one "into which implant is implanted," there is no "target tissue" and summary judgment is warranted. *See Gen. Am. Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 771 (Fed. Cir. 1996).

Dr. Cima attempts to avoid these facts and confuse the jury by arguing that the arm is the "target tissue." By so arguing, Dr. Cima ignores the word "treatment." In his opening report, Dr. Cima points to the Nexplanon Prescribing Information and the Nexplanon Insertion and Removal Guidance, which explain that Nexplanon must be implanted in the patient's arm. *See, e.g.*, Cima Op. Rpt. ¶¶ 57, 65, 116. But as the documents reveal, and as confirmed by Organon's expert, Dr. Kinam Park, these documents only identify the "insertion site" where Nexplanon is "inserted," *i.e.* implanted. Park Rpt. ¶¶ 74–75; *see also* MRK_01055886 (Ex. 6) at 5887 (Nexplanon Prescribing Information); MRK_00540753 (Ex. 7) at 0754 (Nexplanon Insertion and Removal Guidance). They neither refer to that site as the treatment site nor the tissue treated. In his reply report, Dr. Cima stresses how the Nexplanon label provides "specific instructions" for an "exact part" of the upper arm with a "very precise ***target for the implant to be implanted***." Cima Reply Rpt. ¶ 49.[3] In other words, Dr. Cima and the documents on which he relies at best address only one requirement of the Court's construction—the tissue "into which implant is implanted." Dr. Cima's analysis thus ignores the other requirement of the Court's construction—the tissue "***targeted for treatment***"**—**and attempts to collapse the Court's two-requirement construction into one requirement.

Recognizing this lapse in his analysis, Dr. Cima pivoted in his reply report to argue that the arm is the "target tissue for ***delivery*** of etonogestrel" because the arm "is sufficiently vascularized so that systemic ***delivery*** can be achieved indirectly through the vascular compartment." *Id.* ¶ 48. But this effort to substitute "delivery" for "treatment"—which Dr. Cima raised for the first time in his reply report—continues to ignore the word "treatment" in the Court's construction. In his report, Dr. Cima cannot avoid revealing this irreconcilable substitution; in the same paragraph, Dr. Cima goes on to concede that the etonogestrel "acts on," or treats, the "progesterone receptors in specific organs," including "the female reproductive tract, mammary gland, hypothalamus, and pituitary gland." *Id.* Notably, Dr. Cima does not use any form of the word "treatment" when discussing the vasculature of the arm. *See id.* Instead, he talks about why implantation in the arm allows for "systemic ***delivery***" of the contraceptive agent. *Id.* Dr. Cima merely equates the terms "target tissue" and "implantation site." *See id.* Thus, it is Microspherix that attempts to redo claim construction by resurrecting the construction it proposed—"tissue into which implant is implanted"—and the Court rejected. *See* Cima Dep. Tr. 113:9–14 (agreeing that "[t]he implantation site is the same as the tissue into which the implant is implanted"). At bottom, all that Dr. Cima explains is that the arm is targeted ***for implantation***, not treatment. This clear mischaracterization of the Court's construction of the term "target tissue," together with the undisputed facts, warrants summary judgment.

[3] All emphasis from quotes is added unless noted otherwise.

Dr. Cima's deposition testimony underscores how his vascularization argument is all about "implantation" and not "treatment." Dr. Cima testified repeatedly that Organon had to "select a tissue that was sufficiently vascularized" or "choose a tissue that is heavily vascularized" for Nexplanon implantation to have systemic delivery of etonogestrel. *See, e.g., id.* at 112:20–23, 113:2–8, 118:12–19. By contrast, Dr. Cima said that "you can't ***put*** [the implant] in cartilage, which [has] very limited vascularization." *Id.* at 113:2–8; *see id.* at 118:25–119:9 ("[I]f I ***implanted*** it into cartilage, there's very little vascularization, I would not achieve the goal."). Thus, Dr. Cima explained why the arm—and not a place with little vascularization like the forehead—is the site of implantation. *See id.* at 118:25–119:12. This testimony evidences Microspherix's singular focus on the site of implantation, while ignoring the tissue actually targeted for treatment.

Microspherix recognizes the distinction between implantation and treatment and how the precise location of the implant is irrelevant to Nexplanon's treatment of any tissue. Microspherix's OB-GYN expert, Dr. Weinstein, has argued that because etonogestrel is released into the bloodstream and acts systemically, Nexplanon is still contraceptively effective even when it is implanted in the wrong location or in the incredibly rare instances when it migrates within or outside of the arm. Weinstein Op. Rpt. (Ex. 8) ¶ 42 (stating that "irretrievable [Implanon] implants may cause a woman to be unable to conceive") (quotations omitted). Thus, as Dr. Weinstein makes clear, the tissue in which Nexplanon is implanted has nothing to do with the tissue targeted for treatment.

Dr. Cima even testified that the tissues targeted for treatment by Nexplanon are not in the arm. During his deposition, Dr. Cima was asked about the effect of etonogestrel on "where the ovulation-producing hormone is produced." Cima Dep. Tr. 111:17–20. In response, Dr. Cima said that because multiple organs are involved in the production of that hormone, "there's no one single . . . organ that you're ***targeting***. There are multiple organs." *Id.* at 111:22–25. Immediately after, when discussing the relevance of systemic delivery of etonogestrel to those organs—including the pituitary gland, hypothalamus, and mammary gland—he said that "[i]t's not known that [etonogestrel] could be an effective contraceptive if you ***treated*** only one of them." *Id.* at 112:2–16 ("And I can't see that there would be a particular advantage to ***treating*** just one of these organs."). Dr. Cima volunteered testimony that the pituitary gland, hypothalamus, and mammary glands are organs that are targeted for treatment. Accordingly, to the extent that Microspherix asserts that the "vascular compartment" in the arm is targeted for treatment, such assertion conflicts with Dr. Cima's characterization of how etonogestrel ***treats*** specific organs outside the arm to achieve contraception. *See also id.* at 73:25–74:5 (acknowledging that the vasculature in the arm does not have the etonogestrel receptors "that are necessary to have the physiologic effect . . . to prevent fertilization").

The experts agree: the contraceptive Nexplanon is implanted in the arm and treats organs outside the arm. "Because there is no dispute regarding the operation of the accused [device], [this] issue reduces to a question of claim interpretation and is amenable to summary judgment." *MyMail, Ltd. v. Am. Online, Inc.*, 476 F.3d 1372, 1378 (Fed. Cir. 2007). Dr. Cima has only explained why the arm is targeted for implantation, not that it is the tissue treated by the etonogestrel. There is thus no tissue that meets the two requirements of the Court's claim construction. Accordingly, Organon respectfully requests summary judgment of non-infringement of claims 1 and 16 of the '835 patent and claims 1, 13, 16, and 18 of the '401 patent.

Respectfully submitted,

/s/ Cynthia S. Betz

Cynthia S. Betz

cc: All counsel of record